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Diastolic Heart Failure – Innovative Extra and Intra Ventricular Solutions

Mitchell W Krucoff², Lea Lak¹¹CorAssist CardioVascular, Herzliya, Israel; ²Duke University Medical Center/Duke Clinical Research Institute, Durham, NC

Background: Diastolic heart failure (DHF) accounts for over 40% of HF cases. Proven evidence based treatment is lacking. A novel mechanical approach, utilizing energy exerted by the left ventricle (LV) during systole and returning it to the ventricle during diastole to enhance diastolic performance, was realized in two approaches: An Extra-ventricular device (ImCardia™), comprised of elastic springs attached to the LV epimyocardium. A trans apically delivered Intra-ventricular device (CORolla™) comprised of a three-arms spring.

Methods: The ImCardia™ device was implanted as an add-on to AVR (study group, n=10), and compared to AVR only (control group, N=9). The patients were followed up to 24 months to examine indications of safety and efficacy. The CORolla™ device was implanted off-pump in trans-apical approach in healthy sheep (N=26). The sheep were followed up to 9 months. Device acute and chronic safety was evaluated.

Results: ImCardia™: During follow-up period there were no device-related complications or adverse events. Improvement in NYHA functional class, 6-minute walk test and quality of life were similar for both groups. LV mass regression after 18-24 months: -90 gr ± 82 gr in control group Vs -126 gr ± 33 gr in study group. Left atrial area, an important marker of diastolic dysfunction, increased slightly in control group (+1.5 cm² ± 4.09 cm²) but decreased in study group (-2.29 cm² ± 3.09 cm²). CORolla™: good recuperation post implantation with no weight reduction, no EF reduction, good device functionality and safety in follow-up up to 9 months.

Conclusion: A passive extra-cardiac device which transfers energy from systole to diastole, may improve diastolic performance as suggested by further decrease in left atrial size beyond that expected from AVR only; not only the device did not induce LV hypertrophy, it rather demonstrated a trend of LV mass regression enhancement. Using this methodology, an Intra-ventricular elastic device implanted transapically off-pump demonstrated safe profile. Clinical study is planned to start toward end 2011. Percutaneous approach for the intra-ventricular device is in R&D process.

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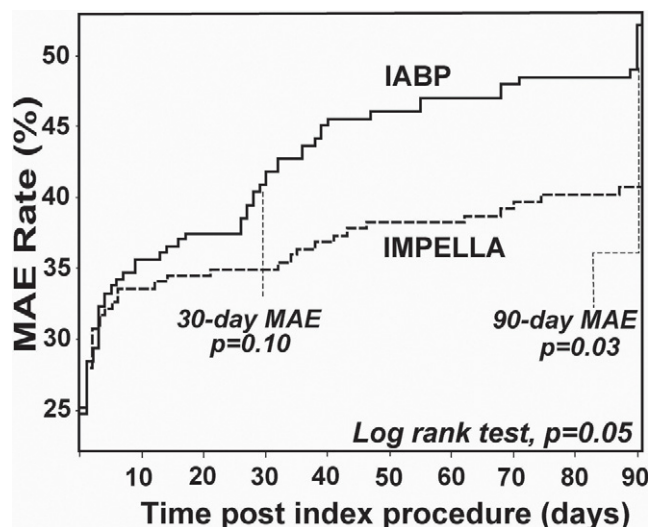
A Prospective Multicenter Randomized Clinical Trial of Intra-aortic Balloon Pump vs Impella for Hemodynamic Support During High Risk PCI: Final Clinical and Angiographic Results of PROTECT II

William O'Neill¹, Neal Kleiman², Simon Dixon³, Joseph Massaro⁴, Brijeshwar Maini⁵, Suresh Mulukutla⁶, Jose Henriques⁷, Vladimir Dzavik⁸, James Revenagh⁹, Hadley Wilson¹⁰, Jeffrey Moses¹¹, Magnus Ohman¹²¹University of Miami, Miami, FL; ²Methodist DeBakey Heart and Vascular Center, Houston, TX; ³William Beaumont Hospital, Royal Oak, MI; ⁴Harvard Clinical Research Institute, Boston, MA; ⁵PinnacleHealth Cardiovascular Institute, Wormleysburg, PA; ⁶University of Pittsburgh Medical Ctr., Pittsburgh, PA;⁷Academic Medical Center, University of Amsterdam, Amsterdam, Netherlands;⁸Toronto General Hospital, Toronto, Canada; ⁹Intermountain Heart Clinic, Salt Lake City, UT; ¹⁰Sanger Heart & Vascular Institute - University of NC, Charlotte, NC; ¹¹Columbia University Medical Center, New York City, NY; ¹²Duke University, Durham, NC

Background: To investigate the potential benefit of Impella 2.5 in high-risk PCI (HRPCI) compared to the intra-aortic balloon-pump (IABP) in a prospective multicenter clinical trial.

Methods: The PROTECT II trial was designed to randomize 654 HRPCI patients who required prophylactic hemodynamic support to Impella or IABP. Patients with 3-vessel disease and LV ejection fraction (LVEF) ≤30%, or with unprotected left main or last patent conduit and LVEF ≤35% were eligible for enrollment. Selection of the revascularization approach was at the discretion of the PCI operator. The primary endpoint was a composite of 10 major adverse events (MAE) at 30 days with a follow-up at 90 days.

Results: Enrollment began in late 11/2007 and reached the 50% mark (n=327) by 02/2010. After pre-specified review of the 50% enrollment data, the Data Safety Monitoring Board recommended termination of the study due to futility on the 30-day primary analysis. At the time of the recommendation (11/2010), the study had reached 68% of the planned enrollment (N=447). The preliminary analysis showed a significant learning curve with Impella, with outcomes improving over the course of the trial. There was a trend for better outcomes at 30 days in favor of Impella for the entire per protocol population (p=0.10). At the 90-day pre-specified follow-up, there was a significant reduction in MAE in favor of Impella (p=0.03, see Figure). The final new clinical and angiographic results of the entire cohort will be presented.



Conclusion: PROTECT II was terminated early on assumptions based on the first half of the data. The analysis of the full cohort provides more insight into the study and suggests positive outcomes over time for the Impella compared to the IABP with a similar safety profile.

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Is It Appropriate To Take All Post-Resuscitation Patients Suspected of Having an Acute MI For Urgent Angiography?

Vivek K Reddy, Vinay R Hosmane, Andrew Doorey, William S Weintraub, Ehsanur Rahman

Cardiology, Christiana Care Health Systems, Newark, DE

Background: Recent studies of patients who have been resuscitated from out-of-hospital cardiac arrest (OHCA) have shown increasing benefit from timely reperfusion therapy for those with STEMI as the etiology. Though no randomized trials have been performed, patients with OHCA with early reperfusion for concurrent STEMI have a mean survival rate of 65%, compared to historical survival of only 25% to 35% for those with only OHCA. The addition of early hypothermia to early reperfusion results in significantly improved neurological function. We reviewed our data to see if OHCA patients who do not fit these criteria were undergoing urgent angiography inappropriately.

Methods: Our facility is a large, academic, community center with around-the-clock catheterization capabilities for STEMI. We retrospectively examined our internal databases of consecutive patients suspected of having STEMI between January 1, 2001 and December 31, 2010. Further data was obtained from electronic hospital records, emergency department records, paramedic records, and the cardiac catheterization database.

Results: Between January 1, 2001 and December 31, 2010, there were 3908 consecutive patients who were suspected of having an MI, 409 of which required CPR. Of these, 240 underwent emergent angiography. In 191 patients a culprit lesion was identified, but in 49 (20%) no culprit lesion was seen. Review of the pre-cath EKGs showed no definitive ST-elevation in 26 of 49 patients (53%). Ventricular fibrillation or tachycardia was the presenting rhythm in 34 patients (69%). During their hospitalization, 26 patients (53%) died.

Conclusion: Even though the favorable outcomes in the available literature are based on STEMI concurrent with OHCA, a significant number of patients who do not have ST-elevation on post-resuscitation EKG are undergoing cardiac angiography emergently. Other measures such as stabilizing hemodynamics, controlling rhythms, and, perhaps most importantly, early initiation of hypothermia are probably more important at this stage when the EKG does not show ST-elevation.

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Cost-effectiveness and Clinical Outcomes of Impella Hemodynamic Support Compared with Intra-Aortic Balloon Pump in High Risk Patients Receiving PCI: Results from the PROTECT II Trial

Brijeshwar Maini¹, William O'Neill², Simon Dixon³, Igor Palacios⁴, Theodore Schreiber⁵, David A Gregory⁶, D. J Scotti⁶¹PinnacleHealth Cardiovascular Institute, Wormleysburg, PA; ²University of Miami, Miami, FL; ³Beaumont Hospital, Royal Oak, MI; ⁴Massachusetts General Hospital, Boston, MA; ⁵Detroit Medical Center, Detroit, MI; ⁶Presscott Associates, Ltd., Avon, CT

Background: Clinical outcomes and cost-effectiveness of new technologies for hemodynamic support in patients with left ventricular dysfunction and complex anatomy have not been previously studied.

Methods: PROTECT II studied patients with 3 vessel disease and LV ejection fraction